

used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

(31) The term ordinary over-the-counter pseudoephedrine or phenylpropanolamine product means any product containing pseudoephedrine or phenylpropanolamine that is—

(i) Regulated pursuant to the Act; and

(ii)(A) Except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches, and

(B) For liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.

(32) The term combination ephedrine product means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers, and therapeutically significant quantities of another active medicinal ingredient.

(33) The term *drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act for distribution in the United States.

(34) The term *valid prescription* means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

[62 FR 13941, Mar. 24, 1997; 62 FR 15392, Apr. 1, 1997; 67 FR 14859, Mar. 28, 2002, as amended at 68 FR 23203, May 1, 2003; 68 FR 57803, Oct. 7, 2003]

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

GENERAL INFORMATION

Sec.

1301.01 Scope of this part 1301.

1301.02 Definitions.

1301.03 Information; special instructions.

REGISTRATION

1301.11 Persons required to register.

1301.12 Separate registrations for separate locations.

1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

1301.14 Filing of application; acceptance for filing; defective applications.

1301.15 Additional information.

1301.16 Amendments to and withdrawal of applications.

1301.17 Special procedures for certain applications.

1301.18 Research protocols.

EXCEPTIONS TO REGISTRATION AND FEES

1301.21 Exception from fees.

1301.22 Exemption of agents and employees; affiliated practitioners.

1301.23 Exemption of certain military and other personnel.

1301.24 Exemption of law enforcement officials.

1301.25 Registration regarding ocean vessels, aircraft, and other entities.

1301.26 Exemptions from import or export requirements for personal medical use.

ACTION ON APPLICATION FOR REGISTRATION; REVOCATION OR SUSPENSION OF REGISTRATION

1301.31 Administrative review generally.

1301.32 Action on applications for research in Schedule I substances.

1301.33 Application for bulk manufacture of Schedule I and II substances.

1301.34 Application for importation of Schedule I and II substances.

1301.35 Certificate of registration; denial of registration.

1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

1301.37 Order to show cause.

HEARINGS

1301.41 Hearings generally.

1301.42 Purpose of hearing.

1301.43 Request for hearing or appearance; waiver.

1301.44 Burden of proof.

1301.45 Time and place of hearing.

1301.46 Final order.

MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION

1301.51 Modification in registration.

§ 1301.01

1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

SECURITY REQUIREMENTS

1301.71 Security requirements generally.

1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

1301.75 Physical security controls for practitioners.

1301.76 Other security controls for practitioners.

1301.77 Security controls for freight forwarding facilities.

EMPLOYEE SCREENING—NON-PRACTITIONERS

1301.90 Employee screening procedures.

1301.91 Employee responsibility to report drug diversion.

1301.92 Illicit activities by employees.

1301.93 Sources of information for employee checks.

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SOURCE: 36 FR 7778, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1301.01 Scope of this part 1301.

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.

[62 FR 13945, Mar. 24, 1997]

§ 1301.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13945, Mar. 24, 1997]

21 CFR Ch. II (4–1–05 Edition)

§ 1301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 23, 1973, and amended at 51 FR 5319, Feb. 13, 1986]

REGISTRATION

§ 1301.11 Persons required to register.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§1301.22–1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

(b) [Reserved]

[62 FR 13945, Mar. 24, 1997]

§ 1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by